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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,748	09/09/2003	Paul J. Thompson	11576.51USC1	3397

7590 04/14/2005

Attention of David G. Schmaltz
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EXAMINER

HOUSTON, ELIZABETH

ART UNIT PAPER NUMBER

3731

DATE MAILED: 04/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary	Application No.	Applicant(s)	
	10/658,748	THOMPSON, PAUL J.	
	Examiner	Art Unit	
	Elizabeth Houston	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>120304, 021904</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: On page 9 in the disclosure, character "18" has been used to designate both the spacer member in the second full paragraph and the splines in the third full paragraph.

Appropriate correction is required.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claim 10-21, 24-29 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-5, 10-13, and 15 of U. S. Patent No. 6,623,491. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the application are merely broader than the patent claims.

4. Claims 10-13, 16-18, 20-22, 24-25, 27 and 29 of this application conflict with claims 1-8, 10-11, 13-14, and 19 amended on 09/13/2004 of Application No. 09/954,763. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 10-18, 20-25 and 27-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Mische et al. (USPN 5,279,546).

7. As to claims 1, 20, 21, and 27, Mische discloses a treatment system (Figures, 1-3), comprising: an elongated outer member (70) having a distal end and a proximal end, the outer member having a wall that defines a first lumen (126, 128, 130, 132); an elongated inner member (72) having a distal end and a proximal end, the inner member having a wall that defines a second lumen (142, 144, 146), the inner member being

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received within the outer member (Col4, line 40-41); the outer member being sized to pass through a body lumen with the distal end being advanced toward a treatment site and with the proximal end being external to the body lumen for manipulation by an operator; the inner member having a treatment region at the distal end of the inner member (86); a fluid passage defined between the wall of the inner member and the wall of the outer member (126, 128, 130, 132); a plurality of circumferentially spaced-apart structures (134, 136, 138, 140) disposed along a majority of the length of the fluid passage between the wall of the inner member and the wall of the outer member with the circumferentially space-apart structures spacing the wall of the inner member from the wall of the outer member; and a port in communication with the fluid passage (46) (Col 4, line 9-10).

8. As to claim 11 and 27, the spaced apart structures extend an entire length from the proximal end of the outer member to the treatment region (the treatment region being defined by balloons (74) and (86)). As to claim 12 and 22, the spaced apart structures are disposed to maintain the inner member centrally positioned within the outer member and prevent the inner member from moving radially (Col 5, lines 32-36). As to claim 23, the spaced apart structures prevent the inner member from contacting the outer member. As to claim 13, 15-18, 24-25 and 29, the spaced apart structures are integral with wall of the inner member and extend radially outward toward the outer member. They define voids along the length of the fluid passage and they extend linearly along a length of the inner member. As to claim 14, the guidewire is element (11).

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 20 and 24-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Krivoruchko et al. (USPN 6,786,918).

11. Krivoruchko discloses a catheter device comprising an elongated outer member (26) having an outer member length and an inner surface that defines a lumen (30), the outer member being sized to be passed through a body lumen; an elongated inner member (24) having an inner member length and positioned within the lumen of the outer member (see figure 2), the inner member including a lumen-defining portion; and a plurality of circumferentially spaced-apart structures (62) that extend between the lumen-defining portion of the inner member and the inner surface of the outer member, the circumferentially spaced-apart structures have an uninterrupted length and are coextensive and with a majority of the lengths of the inner and outer members (Col 4, line 25-26). The spaced-apart structures include a base portion connected to the inner member, and an opposite end that engages the inner surface of the outer member (see Figure 5). The base portions of the spaced apart structures are integral with the lumen-defining portion of the inner member, and the opposite ends are rounded (see Figure 5).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 10-19 and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bevier (USPN 6,190,393) in view of Krivoruchko et al (USPN 6,786,918).

14. Bevier discloses a treatment system, comprising: an elongated outer member (64) having a distal end and a proximal end, the outer member having a wall that defines a first lumen; an elongated inner member (24) having a distal end and a proximal end, the inner member having a wall that defines a second lumen, the inner member being received within the outer member; the outer member being sized to pass through a body lumen with the distal end being advanced toward a treatment site and with the proximal end being external to the body lumen for manipulation by an operator; the inner member having a treatment region at the distal end of the inner member (14); a fluid passage defined between the wall of the inner member and the wall of the outer member (30, Col 4, line 44)); a port in communication with the fluid passage (26); and a guidewire (32).

15. Beveir does not disclose a spacer structure.

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16. Krivoruchko discloses a plurality of circumferentially spaced-apart structures as stated above. In addition Krivoruchko discloses that the spaced apart structures maintain that the inner member is centrally positioned within the outer member (Col 4, line 37). The spaced apart structures are carried on the wall of the inner member, extend radially outward, and define voids (68A-F).

17. It would have been obvious at the time of the invention to one of ordinary skill in the art to combine the spacer structure into the invention of Beveir. The spacer structure decreases space between the members to prevent radial deflection (Col 4, line 37) while at the same time providing lumens for inflating and deflating the balloon. The spacer structure would enhance the invention of Beveir by providing extra support so that the tubular members do not collapse onto each other and so that the tubular members can easily slide independently of each other.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Houston whose telephone number is 571-272-7134. The examiner can normally be reached on M-Th 8:30-6:00 Alternate Fridays 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

eh


GLENN K. DAWSON
PRIMARY EXAMINER